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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/286,818	04/06/1999	RONALD L. REAM	P99.0082	5472

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BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
AHMED, HASAN SYED	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/286,818	REAM ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,19-22 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,19-22 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/7/06, 1/25/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the following: (1) remarks, filed on 7 December 2006; (2) IDS, filed on 7 December 2006; and (3) IDS, filed on 25 January 2007.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the phrase "less than a typical amount" is indefinite as a description of medicament dosage, since the "typical amount" varies from medicament to medicament. Thus, one of ordinary skill in the art would receive no guidance as to dosage based on this standard in view of the multitude of drug classes claimed. The specification may offer guidance for some medicaments such as caffeine or aspirin, but does not offer guidance of what a "typical amount" is for the other drug classes claimed.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-12, 19-22 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aspergum® in view of Gudas, *et. al.* (WO 98/23165).

It is well known in the art that Aspergum® has been commercially available since at least 27 November 1995 (*see* U.S. Patent No. 7,078,052; page 2).

Aspergum® recites:

- the flavors of instant claims 1, 7 and 19 (*see* package, "Inactive Ingredients" under "Drug Facts");
- the chewing of instant claims 1, 7 and 19 (*see* package, "Directions" under "Drug Facts");
- the at least two minutes of chewing of instant claims 2 and 10 (4 hours - *see* package, "Directions" under "Drug Facts");
- the medicament and analgesics of instant claims 1, 4, 7, 8, 9, 19, and 20 (*see* package, "Active Ingredient" under "Drug Facts");
- the chewing of a chewing gum including a medicament at least twice a day of instant claims 5, 12, 19, and 21 (*see* package, "Directions" under "Drug Facts");
- the two pieces of chewing gum chewed at a time of instant claim 22 (*see* package, "Directions" under "Drug Facts"); and
- the blending of the medicament with a base/emulsifier system of instant claim 27 (*see* package, "Inactive Ingredients" under "Drug Facts").

Aspergum® does not recite the use of "less than a typical amount of medicament" as recited in instant claims 1, 7 and 19.

Gudas, et. al. teach a chewing gum containing caffeine (*see* page 2, lines 29-33). The Gudas, et. al. reference teaches a formulation of chewing gum containing a lower concentration of caffeine (1% - *see* page 22, Table 4) than the instant reference (1.8% - *see* Specification, page 15, line 10). Thus, use of "less than a typical amount of a medicament," in view of the instant Specification, is taught by the Gudas, et. al. reference.

The "blending occurs before the providing" limitation of instant claim 28 would have been obvious to a person of ordinary skill in the art at the time was made because the blending of the medicament with a base/emulsifier system must occur before the final product is ready to be provided to the consumer.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a medicament to a chewing gum, as shown by the product Aspergum® in view of the Gudas, et. al. reference. One of ordinary skill in the art at the time the invention was made would have been motivated to add a medicament to a chewing gum in order to provide relief of various symptoms (*see* Aspergum® package, "Uses" under "Drug Facts").

*

2. Claims 1-12, 19-22, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aspergum® in view of Häusler, *et. al.* (U.S. Patent No. 5,922,347).

Aspergum® is a chewing gum formulation containing a medicament (*see* above).

Aspergum® differs from the instant application in that it does not disclose the absorption of a medicament into the systemic system via the oral mucosa, as recited in instant claims 1, 7, and 29.

However, absorption of a medicament in a chewing gum formulation via the oral mucosa was well known in the art at the time the invention was made as shown by Häusler, *et. al.* (*see* col. 2, lines 29-58).

Häusler, *et. al.* explain that this route of administration is beneficial because of rapid absorption and good gastric tolerance (*see* col. 1, lines 40-44).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a chewing gum formulation with a medicament as a method of delivering the medicament into the systemic system via the oral mucosa, as disclosed by the Aspergum® product in view of Häusler, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to use the oral mucosa as a route of administration because of the beneficial effects of rapid absorption and good gastric tolerance, as taught by Häusler, *et. al.*

*

3. Claims 3, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aspergum®.

Aspergum® is a chewing gum formulation containing a medicament (*see* above).

Aspergum® differs from the instant application in that it does not disclose the saliva content of medicament, as recited in instant claims 3, 6, and 11. However, it would have been obvious to one of ordinary skill in the art at the time the invention was

made to determine suitable saliva content of medicament through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant saliva content of medicament.

*

4. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aspergum® in view of Gudas, *et. al.* (WO 98/23165).

Aspergum® is a chewing gum formulation containing a medicament (*see* above).

Aspergum® differs from the instant application in that it does not disclose adjusting the hydrophilic/lipophilic balance of the medicament, as recited in instant claim 26. However, this procedure was known in the art at the time the invention was made, as taught by Gudas, *et. al.* (see page 18, lines 21-24).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to adjust the hydrophilic/lipophilic balance of the medicament in a chewing gum formulation, as disclosed by Gudas, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to adjust the

hydrophilic/lipophilic balance of the medicament in a chewing gum formulation in order to facilitate absorption through the oral mucosa.

* * * * *

Response to Arguments

Applicant's arguments filed on 7 December 2006 have been fully considered but they are not persuasive.

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35 USC 112(2)

Applicants argue that the limitation, "less than a typical amount" is not indefinite. *See* remarks; page 2, 3rd paragraph – page 5, 2nd full paragraph.

Pages 4 and 5 of the Board of Patent Appeals and Interferences opinion regarding this case (mail date 10 September 2004), describes various amounts of aspirin formulations. One of ordinary skill in the art would be aware that aspirin is used for the treatment of headaches as well as for preventing heart attacks, and the amount of aspirin for the treatment of these ailments vary. It is unclear what amount of aspiring fall with in the "less than typical amount" since one cannot determine the exact typical amounts of aspirin to treat headaches or heart conditions since this amount depends on age, weight, gender, and other factors that are patient and population dependent. Thus the metes and bounds of what a typical amount is, is not defined in a manner sufficient to make one of ordinary skill understand what amounts constitute a typical amount, thus the "less than typical amount" can also not be determined.

Likewise, the Board as set forth on page 6, discuss the specification example given as support for their being sufficient explanation of a "typical amount" using the chewing gum formulation with 50 mg of caffeine in comparison with the 100 mg oral tablet dosage. The Board set forth that "even assuming, therefore, that the 'typical amount' of caffeine administered is 100 mg, the specification provides no basis on which to extrapolate that dosage to other agents or medicaments." This argument is still applicable over the instant claims, even though applicants have added the phrase "that is swallowed by the individual to achieve a bioequivalent effect" because there is no basis for determining from the specification what the typical amount would be for all the various types of medicaments. Examiner notes that claim 1 recited a method of delivering a medicament. This is a generic term that encompasses all known medicaments.

One of ordinary skill in the art would recognize that a typical dosage is determined based on many factors such as gender, age, weight, and medical conditions. Thus a typical amount for one patient population might be different than a typical amount from another patient population with differing sets of factors and illnesses. Thus it is not within the level of one of ordinary skill to be able to determine what the various typical dosage amounts would be for all the medicaments known to man, as that amount would needs be determined based on the needs of the patient population being treated.

*

35 USC 103(a)

1. Applicants argue that there is no motivation to combine Aspergum® and Gudas et al. *See* remarks, page 5, last paragraph.

Examiner respectfully submits that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Aspergum® and Gudas et al. disclose a chewing gum containing a medicament. The Gudas et al. reference is invoked to show that use of less than a typical amount of medicament was known in the medicated chewing gum art before the date of the instant application (*see* above).

2. Applicants argue that encapsulation of caffeine by Gudas et al. teaches away from the instant application. *See* remarks, page 6, first full paragraph.

Examiner respectfully submits that encapsulation of caffeine only affects the release profile of caffeine. Once the caffeine is released, the absorption profile will be based on physiological parameters, similar to the instant application.

3. Applicants argue that, "...[Aspergum®] fails to disclose or suggest providing a chewing gum including less than a typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect..." *See* remarks, page 6, second full paragraph.

Examiner respectfully submits that the Gudas et al. reference is relied upon to teach this limitation, as explained in the substantive rejection above.

4. Applicants argue that the Gudas et al. reference, "...fails to disclose or suggest providing a chewing gum including less than a typical amount of medicament than is swallowed by the individual to achieve a bioequivalent effect..." *See* remarks, page 6, second full paragraph.

Examiner respectfully disagrees, as explained in the substantive rejection, above (*see* page 4, 1st paragraph).

5. Applicants argue that [Aspergum® and Gudas et al.], "fail to disclose or suggest chewing the chewing gum to cause the medicament to be released from the chewing gum composition into the buccal cavity of the individual..." See remarks, page 6, second full paragraph.

Examiner respectfully submits that chewing by definition occurs in the oral cavity, thus, any medicament released from chewing gum will inherently release into the buccal cavity, which lines the inside oral cavity.

6. Applicants argue that Aspergum® and Häusler et al. fail to, "disclose or suggest providing a chewing gum including less than a typical amount of medicament than is swallowed by the individual to achieve a bioeqauivalent effect..." See remarks, page 6, last paragraph.

Examiner respectfully submits that the Gudas et al. reference is relied upon to teach this limitation, as explained in the substantive rejection above.

7. Applicants argue that the Office has relied on hindsight reconstruction of the claimed invention. See remarks, page 7, first full paragraph.

Examiner respectfully submits that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HUMERA N SHEIKH
PRIMARY EXAMINER

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